IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 07-468-JJF
	)	
v.	)	**JURY TRIAL DEMANDED**
	)	
RYMED TECHNOLOGIES, INC.,	)	**PUBLIC VERSION**
	)	
Defendant.	)	

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ICU'S MOTION FOR JUDGMENT ON THE PLEADINGS AND/OR FOR PARTIAL SUMMARY JUDGMENT AS TO DEFENDANT'S NINTH AFFIRMATIVE DEFENSE

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I. NATURE AND STAGE OF PROCEEDINGS

Fact and expert discovery have closed, and trial is scheduled to begin January 19, 2010. Plaintiff ICU now seeks partial summary judgment that, as a matter of law, the Ninth Affirmative Defense, which defendant added in April 2009—that United States Patent No. 6,572,592 (the "'592 patent"), is unenforceable due to inequitable conduct— fails to present any triable issue of fact. As a separate ground for dismissal, ICU also invokes Fed. R. Civ. P. 9 and 12(c), which support dismissal on the pleadings alone, particularly in view of *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327-29 (Fed. Cir. 2009), which issued in August 2009.

II. SUMMARY OF ARGUMENT

RyMed's Amended Answer and Counterclaim, (D.I. 87), avers in its Ninth Affirmative Defense that ICU's '592 patent is unenforceable due to inequitable conduct. RyMed's defense fails in two significant ways. First, RyMed has failed to plead the basis with particularity as required under Federal Rule of Civil Procedure 9(b)—it has not set forth sufficient facts to support its allegation of intent to deceive, nor has it identified the particular basis for materiality of the allegedly withheld prior art. Thus, ICU is entitled to judgment on the pleadings against RyMed's inequitable conduct defense.

Should the Court nevertheless deem RyMed's sparse allegations sufficient, RyMed has still not put forth facts to support them. RyMed's defense originally rested on ICU's alleged failure to disclose eleven references to the Patent Office during prosecution of the application that led to ICU's '592 Patent. RyMed has recently agreed to drop nine of the references, leaving only two: 3,831,629 ("Mackal '629") and 3,193,154 ("Bross '154").[1] As to these two references, RyMed has ***no evidence*** that ICU intentionally withheld them in an effort to deceive the Patent

[1] The parties are presently finalizing a stipulation to this effect.

Office. That alone justifies summary judgment. In addition, RyMed lacks any credible evidence that these references, even if intentionally withheld (which they were not), were in any way material to the prosecution of the '592 patent. On these facts, RyMed cannot possibly meet its burden on this inequitable conduct defense, and summary judgment should be granted.

III. STATEMENT OF UNDISPUTED FACTS

A. Prosecution of United States Patent Application 09/569,712

ICU filed United States patent application 09/569,712 (the "'712 application") on May 9, 2000. During prosecution, ICU's attorneys disclosed to the Patent Office a comprehensive set of potential prior art references in three separate Information Disclosure Statements. (Declaration of Daniel Zlatnik ("Zlatnik Decl.", filed herewith) Exs. 1, 2, 3.) For example, on March 18, 2002, ICU attorney Steven J. Nataupsky submitted an information disclosure statement ("March 18, 2002 IDS") that disclosed thirty-four references, each considered by the examiner. (Zlatnik Decl. Ex. 3.) In total, the examiner reviewed 170 references submitted during the three years that the '712 application was pending. (Zlatnik Decl. Exs. 1, 2, 3.) The application issued to Dr. George Lopez as the '592 patent on June 3, 2003 and was assigned to ICU.

B. Prosecution of United States Patent Application 09/989,794

On November 19, 2001, while the '712 application was pending ***before the same examiner***, ICU filed patent application 09/989,794 (the "'794 application"), which was a continuation of the '712 application. During prosecution of the '794 application, around April 10, 2002, Mr. Nataupsky submitted an information disclosure statement ("April 10, 2002 IDS") disclosing several patents to the Patent Office. (Zlatnik Decl. Ex. 4.) Mackal '629 and Bross '154 were among those submitted. (*Id.*) The '794 application issued as U.S. Patent No. 6,682,509 on January 27, 2004 to Dr. George Lopez and was assigned to ICU.

C. RyMed's Ninth Affirmative Defense

On April 16, 2009, RyMed amended its Answer to include a Ninth Affirmative Defense of unenforceability due to inequitable conduct. (D.I. 87 at 6-8.) Although RyMed originally asserted eleven patents, RyMed now alleges that only Bross '154 and Mackal '629 were material to the patentability of the '592 patent, and that ICU or its agents ("ICU", collectively) deliberately withheld these references with the intent to deceive the Patent Office.

RyMed's pleading, reprinted below, alleges few specific facts.

NINTH AFFIRMATIVE DEFENSE

ICU's allegations of infringement of the '592 patent is barred because the '592 patent is unenforceable and in violation of 37 C.F.R. §1.56, the doctrine of inequitable conduct, and the uncomprising duty of candor owed to the United States Patent Office ("PTO") by patent applicants, inventors and their attorneys or agents.

On May 9, 2000, ICU Medical, Inc. filed U.S. patent application S.N. 09/569,712 (the '712 application) which issued as the '592 patent on June 3, 2003. On November 19, 2001 and while the '712 application was pending, ICU Medical, Inc. filed U.S. patent application S.N. 09/989,794 (the '794 application). The '794 application claimed priority to the '712 application and, on information and belief, contains the same invention disclosure as the '712 application.

On information and belief, on or about April 10, 2002, ICU and its attorneys Knobbe, Martens, Olson & Bear, LLP filed a "Second Supplemental Information Disclosure Statement" during prosecution of the '794 application disclosing U.S. Patents 3,193,154; 3,831,629; 5,006,114; 5,439,451; and 5,730,418 as prior art to the '794 application. The '712 application, disclosing the same inventions as the '794 application, was pending at the same time. On information and belief, ICU, the inventors, the prosecuting attorneys and/or agents, and others owing a duty of candor to the PTO failed to disclose the U.S. Patents 3,193,154; 3,831,629; 5,006,114; 5,439,451; and 5,730,418 as prior art in the '712 application. U.S. Patents 3,193,154; 3,831,629; 5,006,114; 5,439,451; and 5,730,418 were materials to the patentability of the claims of the '712 application and '592 patent. On information and belief, ICU, the inventors, the prosecuting attorneys and/or agents, and others owing a duty of candor to the PTO knew or should have known of U.S. Patents 3,193,154; 3,831,629; 5,006,114; 5,439,451; and 5,730,418 prior to issuance of the '592 patent. For example, on or about April 10, 2002, Steven J. Nataupsky of Knobbe, Martens, Olson & Bear, LLP signed the "Second Supplemental Information Disclosure Statement" filed during prosecution of the '794 application that disclosed prior art U.S. Patents 3,193,154; 3,831,629; 5,006,114; 5,439,451; and 5,730,418 as prior art to the '794 application as well as a "Second Supplemental Information

> Disclosure Statement" filed in the '712 application on or about March 18, 2002 that failed to disclose U.S. Patents 3,193,154; 3,831,629; 5,006,114; 5,439,451; and 5,730,418.
>
> Upon information and belief, the failure by ICU, the inventors, the prosecuting attorneys and/or agents, and others owing a duty of candor to the PTO to disclose U.S. Patents 3,193,154; 3,831,629; 5,006,114; 5,439,451; and 5,730,418 as prior art in the `712 application during prosecution of the '592 patent was knowing, willful, and made with intent to deceive. This failure to disclose with intent to deceive constitutes inequitable conduct and unclean hands that renders the '592 patent unenforceable.
>
> On information and belief, on or about June 27, 2003, ICU and its attorneys Knobbe, Martens, Olson & Bear, LLP filed a "Fourth Supplemental Information Disclosure Statement" during prosecution of the '794 application disclosing, among other prior art patents, U.S. Patents 2,696,212; 2,935,067; 3,734,080; 3,886,930; 4,256,106; and 5,067,950 as prior art to the '794 application. On information and belief, ICU, the inventors, the prosecuting attorneys and/or agents, and others owing a duty of candor to the PTO failed to disclose the U.S. Patents 2,696,212; 2,935,067; 3,734,080; 3,886,930; 4,256,106; and 5,067,950 as prior art in the '712 application. U.S. Patents 2,696,212; 2,935,067; 3,734,080; 3,886,930; 4,256,106; and 5,067,950 were materials to the patentability of the claims of the '712 application and '592 patent. On information and belief, ICU, the inventors, the prosecuting attorneys and/or agents, and others owing a duty of candor to the PTO knew or should have known of U.S. Patents 2,696,212; 2,935,067; 3,734,080; 3,886,930; 4,256,106; and 5,067,950 prior to issuance of the '592 patent.
>
> Upon information and belief, the failure by ICU, the inventors, the prosecuting attorneys and/or agents, and others owing a duty of candor to the PTO to disclose U.S. Patents 2,696,212; 2,935,067; 3,734,080; 3,886,930; 4,256,106; and 5,067,950 as prior art in the '712 application during prosecution of the '592 patent was knowing, willful, and made with intent to deceive. This failure to disclose with intent to deceive constitutes inequitable conduct and unclean hands that renders the '592 patent unenforceable.

(D.I. 87 at 6-8.) As shown above, RyMed pleads no facts explaining the materiality of the allegedly withheld references, instead only stating its conclusion that these two references, among others, "were material." RyMed similarly bases its accusation of specific intent to deceive solely on "information and belief" and the fact that Mr. Nataupsky submitted an IDS in March 2002 that did not include those references

IV. RYMED'S NINTH AFFIRMATIVE DEFENSE FAILS ON THE PLEADINGS

As a preliminary matter, this Court can dispose of the Ninth Affirmative Defense without reaching the summary judgment question, for the defense fails on the pleadings alone.

Federal Rule of Civil Procedure 9(b) requires allegations of fraud "to be stated with particularity." Courts routinely consider challenges to the sufficiency of such allegations as motions to dismiss under Rule 12(b)(6), judgment on the pleadings under Rule 12(c), or simply as motions pursuant to Rule 9(b). *See, e.g., In re Alpharma Sec. Litig.*, 372 F.3d 137, 153 (3d Cir. 2004) (affirming Rule 12(b)(6) dismissal of claim for failure to comply with Rule 9(b)); *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984) (considering "motion to dismiss under Rule 9(b)"); *cf. Turbe v. Government of Virgin Islands, 938 F.2d 427*, 428 (3d Cir. 1991) (same standard applies for Rule 12(c) and Rule 12(b)(6) motions).

A. Heightened Pleading Standards Apply to Inequitable Conduct Claims, Which Are Generally Disfavored Under Federal Law.

It is well settled that Rule 9(b) applies to allegations of inequitable conduct. *Ferguson Beauregard/Logic Controls, Div. of Dover Res. ,Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 2009 U.S. Dist. LEXIS 97852, at *2-3 (D. Del. Oct. 19, 2009). Thus, a party asserting inequitable conduct must set forth the particularized factual basis for its allegations, including "explicit rather than implied expression of the circumstances constituting fraud." *King Auto, Inc. v. Speedy Muffler King, Inc.*, 667 F.2d 1008, 1010 (C.C.P.A. 1981)). Moreover, although Rule 9(b) permits "conditions of mind" to be averred generally, a pleading must allege sufficient underlying facts from which a court may reasonably infer that a specific individual acted with the requisite state of mind. *Exergen*, 575 F.3d at 1327-29; *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997).

For inequitable conduct, this state of mind includes both (1) knowledge of the withheld information and (2) specific intent to deceive the PTO. *Exergen* 575 F.3d at 1330.

RyMed's Ninth Affirmative Defense fails to set forth the particularized basis for inequitable conduct, leaving the necessary supporting facts to be inferred. Accordingly, ICU is entitled to judgment on the pleadings as a matter of law.

B. RyMed Fails To Plead Sufficient Underlying Facts To Support Its Allegation of Deceptive Intent.

First, RyMed fails to raise facts sufficient to support an inference of knowledge and specific intent to deceive. RyMed alleges deceptive intent based only on "information and belief." (D.I. 87 at 6-8.) But inequitable conduct allegations based on "information and belief" must set forth the "specific facts upon which the belief is reasonably based." *Exergen*, 575 F.3d at 1331. RyMed has not done that here. Instead, the only "support" RyMed alleges is the fact that ICU's attorney submitted allegedly material references during prosecution of the separate '794 application, ***a month after*** he had filed the March 18, 2002 IDS in the '712 application. (D.I. 87 at 6-7.) RyMed never alleges that Mr. Natauspky actually knew about the Bross and Mackal patents when he submitted the March 18, 2002 IDS, and it certainly does not allege that Mr. Nataupsky knew of any specific information within those references that was material to the '712 application. (*See id.* at 6-8.)

As the Federal Circuit reiterated in *Exergen*, even if an individual knows of a reference in general, "one cannot assume that [that] individual . . . also knows of the specific material information contained in that reference." *Exergen*, 575 F.3d at 1330; *see FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987). In fact, when presented with nearly identical facts, the Federal Circuit in *Exergen* explicitly rejected the allegation on which RyMed's entire defense is premised: "The mere fact that an applicant disclosed a reference

during prosecution of one application, but did not disclose it during prosecution of a related application, ***is insufficient*** to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct." *Exergen*, 575 F.3d at 1331. (emphasis added). RyMed's pleading fails under Rule 9(b) because it cannot support an inference that ***any*** individual acted with the requisite knowledge of materiality, and it certainly cannot support the broad accusation regarding "ICU, the inventors, the prosecuting attorneys and/or agents, and others owing a duty of candor". (D.I. 87 at 7.) *Exergen*, 575 F.3d at 1330; *see also Strange v. Nationwide Mut. Ins. Co.*, 867 F. Supp. 1209, 1219-20 (E.D. Pa. 1994) (complaint alleging fraud by unidentified agents of defendants did not satisfy particularity requirements of Rule 9(b)); *Manual of Patent Examining Proc.* ("MPEP") § 2001.01 (8th ed., rev.2, May 2004) ("the duty applies only to individuals, not to organizations.").

C. RyMed Fails To Plead Material Omission with Sufficient Particularity.

The Federal Circuit's decision in *Exergen* provides further guidance on the issue of "materiality," which RyMed has also failed to properly plead. The pleading in *Exergen* did not identify specific claim limitations to which the allegedly withheld references were relevant, nor did it pinpoint the allegedly material information within those references. *Exergen*, 575 F.3d at 1329. The pleading stated only generally that the withheld references were "material" and "not cumulative to the information already of record." *Id.* This was insufficient under Rule 9(b). *Id* at 1329-30.

Just as in *Exergen*, RyMed's Ninth Affirmative Defense fails to plead a sufficient factual basis for its allegations. RyMed does not identify any claim limitations to which omitted references are relevant, nor does it identify where in those references material information is located. (D.I. 87 at 6-8.) Instead, RyMed offers only the conclusion that references "were

material[] to the patentability of the claims of the '712 application and '592 patent." (*Id.* at 7.) These are precisely the vague allegations deemed insufficient in *Exergen*. *See Exergen*, 575 F.3d at 1329-30. RyMed's pleading fails to meet the particularity requirements of Rule 9(b) as to materiality, and judgment on the pleadings is proper. *See id.* at 1329-30.

V. SUMMARY JUDGMENT SHOULD BE GRANTED IN ICU'S FAVOR ON RYMED'S NINTH AFFIRMATIVE DEFENSE FOR INEQUITABLE CONDUCT

Even if the Ninth Affirmative Defense is deemed sufficiently pled, it fails on summary judgment, for RyMed does not have the clear and convincing evidence necessary to support it. RyMed still presents no genuine issue as to the materiality of the Bross or Mackal references, and it has no evidence that these references were intentionally withheld, beyond the "information and belief" alleged in its Answer. Summary judgment as to RyMed's Ninth Affirmative Defense is proper.

A. Summary Judgment Standard and Inequitable Conduct

Federal Rule of Civil Procedure 56 permits a court to grant summary judgment on a particular defense when a party is entitled to judgment as a matter of law on that defense. Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Summary judgment is appropriate when there is insufficient evidence to enable a reasonable fact finder to decide in favor of the nonmoving party. *Gen. Mills., Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 980 (Fed. Cir. 1997).

1. The Charge of Inequitable Conduct

Inequitable conduct requires a threshold showing that those prosecuting a patent failed to disclose material information, misrepresented material facts, or submitted false, material information, and did so with the specific intent to deceive the patent examiner. *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.2d 1321, 1327 (Fed. Cir. 1998); *Star Scientific, Inc. v. R.J. Reynolds*

Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008); 37 CFR § 1.56 (applicants have "a duty to disclose to the Office all information *known to that individual to be material* to patentability . . . .") (emphasis added).

Information may be material under either 37 C.F.R. § 1.56(b) ("PTO Rule 56") or the older "reasonable examiner" standard. *Rentrop v. Spectranetics Corp.*, 550 F.3d 1112, 1119 (Fed. Cir. 2008). Under the version of PTO Rule 56 in force during prosecution of the '592 patent:

> [I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
> (1) It establishes, by itself or in combination with other information, a
> prima facie case of unpatentability of a claim; or
> (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.[2]

37 C.F.R. § 1.56. Under the earlier "reasonable examiner" standard, "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." *Cargill, Inc v. Canbra Foods, Ltd,* 476 F3d 1359, 1364 (Fed Cir 2007) (quoting 37 CFR § 1.56(a) (1991)). Under either standard, nondisclosure of cumulative references is not a basis for inequitable conduct. *See Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 992 (Fed. Cir. 1988).

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[2] This "new" Rule 1.56 is "applicable to all applicants and reexamination proceedings pending or filed after the effective date [March 16, 1992]." 57 Fed. Reg. 2021 (Jan. 17, 1992) (codified at 37 C.F.R. § 1.56). Before 1992, the PTO rule was the "reasonable examiner" standard. *See Molins P.L.C. v. Textron, Inc.*, 48 F.3d 1172, 1179 (Fed. Cir. 1995).

2. The Standard for Inequitable Conduct Claims on Summary Judgment

When evaluating the sufficiency of the evidence on a summary judgment motion for inequitable conduct, the court must consider the standard of proof, which requires a showing of materiality and intent by clear and convincing evidence. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1570-71, 1582-83 (Fed. Cir. 1991), *partially overruled on unrelated issue by Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 , 1291 (Fed. Cir. 2009); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (U.S. 1986) ("in ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burden."). This high burden requires "evidence which proves in the mind of the trier of fact 'an abiding conviction that the truth of [the claimant's] factual contentions [is] 'highly probable.'" *Intel Corp. v. United States Int'l Trade Comm'n*, 946 F.2d 821, 830 (Fed. Cir. 1991) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984).) Thus, inequitable conduct claims are routinely disposed of on summary judgment, such as where undisputed facts show that the party alleging inequitable conduct cannot present clear and convincing evidence of a misrepresentation or omission, materiality or intent. *See, e.g.*, *Scripps*, 927 F.2d at 1582-83 (affirming summary judgment against inequitable conduct because the evidence could not meet the clear and convincing standard); *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998) (same); *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1306 (Fed. Cir. 2000) (same).

If either materiality or intent is lacking, no further analysis need be performed and unenforceability must be denied. *Id.* at 1261; *Monon Corp. v. Staughton Trailers, Inc.*, 239 F.3d 1253, 1262 (Fed. Cir. 2001). In this case, RyMed's Ninth Affirmative Defense lacks both.

3. RyMed Has Failed To Raise An Issue Of Material Fact Regarding Deliberate Withholding of Information Material to Patentability of the '592 Patent.

RyMed has failed to add any meaningful substance to its bare accusation of intent. Inequitable conduct requires a showing of specific intent, including both knowledge that the withheld information was material and the intent to deceive. *Star Scientific*, 537 F.3d at 1366; *see Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995); 37 CFR § 1.56. Moreover, an inference of specific intent must be the "most reasonable inference able to be drawn from the evidence." *Star Scientific*, 537 F.3d at 1366. Far from establishing a reasonable inference, RyMed has established no competent evidence that any individual believed that either the Bross or Mackal references were material to patentability of the '712 application. There is no issue of material fact regarding specific intent, and RyMed's inequitable conduct defense cannot survive summary judgment.

RyMed's only allegation is that ICU's prosecuting attorney, Mr. Nataupsky, committed inequitable conduct by not disclosing Bross '154 and Mackal '629. RyMed asserts two vague and unsupported facts to support this contention. [redacted] Second, RyMed argues that Mr. Nataupsky's submission of a March 18, 2002 IDS in the '712 prosecution that did not disclose the Bross and Mackal references also supports a finding of intent. (D.I. 87 at 7.) Neither allegation is sufficient to meet the high burden RyMed carries on inequitable conduct.

[redacted]

[redacted]

Moreover, as discussed in the previous section, the mere fact that Mr. Nataupsky disclosed these two references, among others, during prosecution of the '794 application but not in connection with the related '712 application does not show deceptive intent. The Federal Circuit addressed this exact argument in *Exergen Corp.* and held it could not "meet the threshold level of deceptive intent." 575 F.3d at 1331. This argument is even less appropriate here, where the same examiner processed both the '712 and '794 applications. *See Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1456 (Fed. Cir. 1984) (refusing to read any nefarious purpose into the fact that references had been included in co-pending applications before the same examiner, which undercut contention that plaintiff "affirmatively misled" the examiner). As if this weren't enough, Mr[redacted]

RyMed's second argument, regarding Mr. Nataupsky's submission of the March 18, 2001 IDS to the Patent Office, fares no better. RyMed presents no evidence that Mr. Nataupsky knew

of the Bross and Mackal references at any time before April 10, 2002 or that he believed them to be material to the '712 application. *See Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 ("Intent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding of deceptive intent."); *FMC Corp.*, 835 F.2d at 1415 (requiring actual knowledge of the material information).

[redacted] Without evidence that an individual intentionally avoided learning of materiality, RyMed cannot prove inequitable conduct. *See FMC Corp.*, 835 F.2d at 1415 ("an applicant must be chargeable with knowledge of the materiality of the art").

4. The Evidence Cannot Establish That Bross '154 and Mackal '629 Were Material to the Patentability of the '592 Patent.

While RyMed's claim already fails because it cannot prove the required "intent," for completeness, ICU also addresses the "materiality" requirement.[5] Here too, RyMed fails.

[redacted]

As ICU explains below, none of these arguments supports "materiality". In addition, ICU addresses RyMed's failure to demonstrate that Mackal and Bross are not cumulative of the references cited. A reference is material ***only if*** it is "not cumulative to information already of

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[4] What ICU knew or did not know is similarly irrelevant. The duty to disclose applies to individuals, not organizations. MPEP § 2001.01.

[5] RyMed provided no argument or evidence in support of the other ground for materiality under Rule 56: that a reference is inconsistent with a position taken by the applicant during prosecution. Thus, ICU does not address it here.

record or being made of record in the application." 37 C.F.R. 1.56(b). [redacted] *See Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 992 (Fed. Cir. 1988) (holding that nondisclosure of cumulative references is not a basis for inequitable conduct).

a. Bross '154 Does Not Render Claim 45 Obvious in Combination With Vaillancourt '927.

[redacted] There are several problems here.

Claim 45 covers:

> A method of transferring a predetermined amount of medication from a remote source to a patient [592 a], including
>
> (a) connecting a medical valve to the patient [592 b] where the valve includes an opening sufficiently large to receive a delivery end of a medical implement which transfers said predetermined amount of medication through said delivery end into the valve [592 c], said valve including an enclosed spike with a tip having a hole therein [592 d] and a resilient seal which is adapted to be moved into a compressed state by the delivery end upon insertion of said delivery end of the medical implement into said valve and an returns to a decompressed state upon removal of said delivery end to close said valve [592 e], said delivery end and said seal being adapted to engage so that the tip of the spike pierces the seal and there is essentially no dead space between said delivery end and the seal [592 f];
>
> (b) inserting the delivery end of the medical implement into said valve and pushing said delivery end against said seal to compress said seal sufficiently to allow said tip of the spike to pierce the seal [592 g] and enter said delivery end, said seal and delivery end engaging to eliminate essentially any dead space [592 h];
>
> (c) transferring from the remote source to the patient directly through said valve essentially the entire predetermined amount of medication, so that essentially none of said predetermined amount is collected in any dead space in the valve [592 i]; and

> (d) withdrawing the delivery end of the medical implement from the valve to enable the seal to return to the decompressed state to close the valve and maintain while in said decompressed state a fluid tight seal even at high pressures and repeated uses [592 j].

At the outset, this combination is suspect because Vaillancourt '927 was disclosed to the examiner. In addition, Bross relates to a snap closure, similar to those used in sports water bottles today, and Mackal to a check valve, neither of which could be considered analogous art in the first place.

Turning to the combination itself, the first flaw relates to [592a], "A method of transferring a predetermined amount of medication from a remote source to a patent." [redacted] Thus, under RyMed's theory, Bross '154 can at most be cumulative with respect to element [592a]. RyMed's theory aside, it is clear that Bross '154 does not disclose the delivery of medication to a patient. (*See* Zlatnik Decl. Ex. 5 [Bross] at 4:17-24, 9:1-20, cited by RyMed at Zlatnik Decl. Ex. 11at 106.) Bross '154 is not material with respect to limitation [592a].

RyMed next moves to [592c], "where the valve includes an opening sufficiently large to receive a delivery end of a medical implement which transfers said predetermined amount of medication through said delivery end into the valve." This is flawed for a similar reason. Vaillancourt '927 discloses a connector with a female adaptor into which a syringe or luer can be inserted. (Zlatnik Decl. Ex. 7 at 5:49-58, Figs 3-4.) [redacted] Bross does not teach the

connection between a medical implement and a valve having an opening large enough to receive a medical implement. (*See* Zlatnik Decl. Ex. 5 [Bross].) Thus, it is not material with respect to limitation [592c].

The next relevant limitation is [592i], "transferring from the remote source to the patient directly through said valve essentially the entire predetermined amount of medication, so that essentially none of said predetermined amount is collected in any dead space in the valve."

[redacted] Once more, Bross '154 is at most cumulative. However, as explained above with respect to limitation [592a], this patent does not teach delivery of a predetermined amount of medication to a patient, so it is not relevant in any event.

[redacted] There is nothing material about Bross '154 with respect to limitation [592i].

Finally, RyMed cites limitation [592 j], "withdrawing the delivery end of the medical implement from the valve to enable the seal to return to the decompressed state to close the valve and maintain while in said decompressed state a fluid tight seal even at high pressures and repeated uses." [redacted] To the contrary, Bross '154 teaches a "closure means" that can be locked or unlocked, and can be made responsive to pressure so that pressure can ***open*** (not close) the closure means to discharge fluid. (Zlatnik Decl. Ex. 5 at 1:35-42, 5:33-38, 5:62-70.) Although the closure means can be locked-closed to be fluid tight, (*id.* at 3:41-55), nothing in the patent suggests a seal that has a

decompressed state and is designed to remain fluid tight "even at high pressures and repeated uses." Bross '154 is not material with respect to this limitation, at least because it cannot support obviousness in combination with Vaillancourt '927.

[redacted] As a result, it does not establish a prima facie case of unpatentability, nor would a reasonable examiner have considered this reference important in determining patentability. This proposed combination provides no evidence of materiality. *See Rentrop*, 550 F.3d at 1119.

b. Bross '154 Does Not Render Claim 45 Obvious In Combination With Vaillancourt '927 and Dudar '394, or in Combination With Vaillancourt '927 and Lueders '369.

[redacted] Thus, besides being unnecessarily convoluted, these allegedly obvious combinations underscore how Bross '154 is at most cumulative of Vaillancourt '927 and Dudar '394, both of which were disclosed during the prosecution of the '712 application. Thus, these obviousness contentions fail to demonstrate materiality as well.

[redacted] RyMed's position that such a

[6] Leuders '369 was not of record during the '712 application.

combination teaches limitation [592a] precludes Bross '154 from being material; even if it taught this limitation, under RyMed's theory it would be cumulative of Vaillancourt '927 and Dudar '394.

[redacted] Therefore, even if Bross '154 taught this limitation which it does not), it would merely be cumulative of Vaillancourt '927 and Dudar '934, each of which includes drawings and descriptions of devices with openings designed to receive medical implements. (*See* Zlatnik Decl. Ex. 8 at Figs. 4A, 4B, 7:52-59; Ex. [Vaillancourt '927] at Figs 3, 4, 5, 5:15-22, 5:49-58.)

RyMed also demonstrates that Bross '154 is cumulative with respect to element [592i], "transferring from the remote source to the patient directly through said valve essentially the entire predetermined amount of medication, so that essentially none of said predetermined amount is collected in any dead space in the valve." [redacted] Therefore, even if Bross '154 taught any part of this limitation (which it does not), under RyMed's theory it would be cumulative of either Vaillancourt '927 or Dudar '394.

[redacted]

d. Bross '154 and/or Mackal '629 Do Not Render Claim 1 Obvious In Combination With Bonaldo '703.

[redacted]

As a threshold matter, ICU has not asserted claims 1, 3 and 5 of the '592. And because of this, the Court has not construed significant terms in these claims, such as the "pressure responsive element." [redacted]

But even if RyMed were to somehow move past the claim construction issue, which it cannot, RyMed still fails to identify a pressure responsive element in Bonaldo '703 that even approaches the element as disclosed and claimed in the '592 patent. (*See id.*; Zlatnik Decl. Ex. 9.) The abstract describes the invention as including a "self-sealing valve element," but this does not disclose the claimed pressure responsive element. (*See id.*) In fact, the specification never even uses the word "pressure" to describe how the claimed catheter function, except in the context of "finger pressure," which is apparently not required to prevent backflow of blood into the catheter. (*Id.* at 5:36-52.)

Because Bonaldo '703 does not disclose a pressure responsive element (even assuming that it can somehow be defined without a full *Markman* hearing) and no other prior art is alleged

to supply this limitation, the combination of Bonaldo '703, Mackal '629, and Bross '154 cannot establish prima facie unpatentability of claim 1. *See* 37 C.F.R. 1.56(b). A finding of materiality based on these facts is thus impossible. *See id.* ("information is material to patentability when it is not cumulative . . . and (1) it establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim.").

Because claims 3 and 5 depend from claim 1, Mackal '629 and Bross '154 are not material with respect to those claims for at least the reasons discussed above.

VI. CONCLUSION

RyMed's Ninth Affirmative Defense fails at the pleading stage and on the merits. RyMed did not have sufficient evidence regarding materiality and intent when it plead this defense, and it still does not have such evidence even after fact and expert discovery have closed. Indeed, no such evidence exists. ICU's motion should be granted and RyMed's Ninth Affirmative Defense should be either dismissed on the pleadings or dismissed summarily under Fed. R. Civ. P. 56.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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